

In the claims, kindly add the following new claims 50-64.

50. The method of claim 2, wherein the characteristic of the biological fluid is the concentration of glucose.

51. A method for harvesting interstitial fluid from tissue and analyzing the interstitial fluid, comprising steps of:

- porating a selected area of skin to form an opening for extracting a sample comprising interstitial fluid, which sample is suitable for quantitating an analyte;
- collecting the sample from the skin opening, wherein step (b) is enhanced by applying a vacuum to the selected area of the skin, and further wherein the sample is collected in an article comprising (i) a pad capable of receiving an interstitial fluid sample; and (ii) a strap or adhesive tape for holding the pad to the selected area of the skin, wherein the article contains an opening suitable to allow the sample to contact the pad; and
- determining the amount of analyte within the sample.

52. A method for harvesting biological fluid from tissue and analyzing the biological fluid, comprising:

- providing a multi-layer integrated device comprising:
  - a receiving layer capable of receiving a sample of biological fluid including an analyte and facilitating the movement of the fluid;
  - an analyte sensor capable of detecting the presence of analyte or measuring the concentration of analyte in the fluid;
  - a substrate layer that is capable of being in contact with a processing circuit, and

(iv) a bottom layer; wherein the receiving layer (i) is located underneath at least a portion of the substrate layer (iii) and wherein said substrate layer (iii) has at least one opening therein;

b. forming an opening in an area of skin suitable for extracting a sample of biological fluid suitable for measuring a characteristic of the fluid;

c. extracting the sample from the skin opening and introducing the sample into the integrated device, wherein at least one of positive and negative pressure is employed in order to enhance the extraction of the sample; and

d. measuring a characteristic of the biological fluid.

53. The method of claim 52 wherein the biological fluid comprises blood.

54. The method of claim 52 wherein the biological fluid comprises interstitial fluid.

55. An apparatus for obtaining interstitial fluid for diagnostic testing comprising:

a. a device for porating a selected area of skin to extract a sample comprising interstitial fluid; and

b. a vacuum device for introducing a vacuum onto the selected area of skin so as to enhance fluid flow from the skin, wherein the device is capable of controlling the pressure level and/or timing of the vacuum.

56. The apparatus according to claim 55 wherein the vacuum is capable of being maintained at a desired pressure level.

57. An apparatus for obtaining biological fluid for diagnostic testing comprising:

a. a device for forming an opening in an area of skin suitable for extracting a sample of biological fluid; and

b. a mechanical device for introducing a positive pressure to the area of skin to assist in the fluid flow from the opening, wherein the device is capable of controlling the timing and/or the amount of pressure on the skin.

58. The apparatus according to claim 57 further comprising a vacuum device for introducing a vacuum onto the selected area of skin so as to enhance fluid flow from the opening, wherein the device is capable of controlling the pressure level and/or timing of the vacuum.

59. The apparatus of claim 57 wherein the sample comprises blood.

60. The apparatus of claim 57 wherein the sample comprises interstitial fluid.

61. A method for harvesting biological fluid from tissue and analyzing the biological fluid, comprising steps of:

- placing a layer in contact with a surface of tissue;
- forming at least one hole in the tissue;
- collecting biological fluid from the tissue through at least one opening in the layer; and
- wetting a sensor that is positioned in fluid communication with the at least one opening in the layer with biological fluid to measure a characteristic of the biological fluid, wherein the process further comprises applying positive pressure to the layer so as to induce flow of biological fluid through the opening.

62. A method for harvesting biological fluid from tissue and analyzing the biological fluid, comprising steps of:

- placing a layer in contact with a surface of tissue;
- forming at least one hole in the tissue;
- collecting biological fluid from the tissue through at least one opening in the layer; and
- wetting a sensor that is positioned in fluid communication with the at least one opening in the layer with biological fluid to measure a characteristic

of the biological fluid and wherein the process further comprises the step of creating a negative pressure to the skin so as to induce flow of biological fluid through the opening.

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63. An integrated fluid harvesting and analysis device, comprising:

- a first layer having a porating element disposed thereon, the porating element forming at least one opening in the tissue;
- a sensor positioned in fluid communication with the at least one opening in the tissue, the sensor being responsive to a biological fluid collected from the tissue to provide an indication of a characteristic of the biological fluid; and
- a mechanical element having a small opening therein and capable of receiving the integrated device such that the porating element is aligned with the small opening, the mechanical element responsive to downward force thereon to cause the surface of the tissue to bulge into the small opening.

64. An integrated fluid harvesting and analysis device, comprising:

- a first layer having a porating element disposed thereon, the porating element forming at least one opening in the tissue;
- a sensor positioned in fluid communication with the at least one opening in the tissue, the sensor being responsive to a biological fluid collected from the tissue to provide an indication of a characteristic of the biological fluid, and
- sealing means for pneumatically sealing the integrated device to the surface of the tissue and forming a sealed chamber, and means coupled to the sealing means for supplying negative pressure to the sealed chamber.